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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,644	03/18/2005	Young Chul Sung	428.1049	2017

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,644	SUNG ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-17 and 19-37* is/are pending in the application.

4a) Of the above claim(s) *30-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-17 and 19-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed November 26, 2007 in response to the Office Action of May 24, 2007 is acknowledged and has been entered. Claims 1, 2, 4-6, 15-17, 19, 20, and 30 have been amended. Claims 1, 2, 4-17, and 19-29 are under examination in the present Office action.

Claim Objections

Objection to claim 15 **is withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 1, 2, 4-17, and 19-29 under 35 U.S.C. 112, first paragraph, with regard to the biological deposit of the plasmids of the present invention **is withdrawn** in view of Applicant's declaration filed November 26, 2007.

Rejection of claims 1, 2, 4-17, and 19-29 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicants argue that the vaccine composition of the present invention induced optimal levels of cellular immune response to HCV in vaccinated and HCV challenged chimpanzees, and reduced viral titers 10 to 100 fold. In response to Applicants arguments the Examiner acknowledges that the specification provides evidence that the compositions of the present invention were shown to induce HCV specific cellular immune responses in chimpanzees. It is also acknowledged that Applicants

conducted challenge experiments in vaccinated chimpanzees. Working examples 12 and 16 discuss immunization and challenge experiments in chimpanzees. Example 12 refers to Figure 15 in the drawings, and Table 1.Figure 15 shows vaccination and challenge schedule and Table 1 provides general information with regard to chimpanzee's age and exposure to HBV and HCV. Example 16 discusses quantification of HCV in challenged chimpanzees using quantitative PCR. Figure 19 shows the results of the quantitative PCR. However, the results of the HCV measurement in Figure 19 show detectable levels of HCV, at two weeks post challenge in chimpanzee designated as "400" and in chimpanzees "397" and "402". The results show even higher levels of HCV at four weeks post challenge as compared to two weeks post challenge, see" chimpanzee 381, 397, and 402. Only one chimpanzee 393 showed undetectable levels of HCV at two and four weeks post challenge. Thus Applicant's experimental results clearly indicate that the vaccine composition of the present invention was not effective in preventing HCV infection in chimpanzees. While the compositions of the invention are effective in inducing HCV specific cellular immune responses, the induced immune response are not sufficient to prevent HCV infection in chimpanzees. Therefore it is the Office's position that the present specification does not provide sufficient support for the claimed vaccines.

In view of the fact that an effective HCV vaccine for human use does not currently exist, and the obstacles associated with the development of a protective HCV vaccine, as well as experimental results provided in the present Application, as discussed on the record in the Office action of May 24, 2007, it is the Office's position that it would have been rather unpredictable that the compositions of the invention could be useful as vaccines for human use.

Applicants also argue that Patents drawn to HCV vaccines have been allowed by the USPTO. Applicants cite a number of Patents that disclose HCV vaccine compositions. In response to Applicant's arguments the Office notes that the claims of the Patents cited by the Applicants do not recite "HCV vaccines".

It is also noted that the determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112, 1 is conduced on a case-by-case basis. In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 the Office considers the factors of In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. In the present case, the lack of protection from HCV infection in chimpanzees, as discussed above, as well as the unpredictability in the art with regard to HCV vaccination, do not permit the skilled artisan to reasonably conclude that the compositions of the present inventions could be used as protective vaccines in chimpanzees or in humans. Thus in view of the teachings in the art and the working examples in the present specification it is the Office's position that the Applicants have not provided sufficient enablement for the claimed vaccines.

Thus in view of the above the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Rejection of claims 1, 2, 6, 16, and 21 under 35 U.S.C. 102(b) as being anticipated by Saito et al. (US Patent 5,731,172) **is maintained.**

Rejection of claims 1, 2, and 6 under 35 U.S.C. 102(e) as being anticipated by Tang et al. (US 2004/0166488 A1) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicants amended the claims to recite that the first DNA plasmids comprised in the claimed vaccine contains DNA fragments encoding structural proteins composed of core E1 and E2, the second plasmid containing DNA fragment encoding non-structural HCV protein composed of NS3 and NS4, and the third plasmid containing DNA fragment encoding HCV NS5. Applicants argue that Saito et al. do not disclose a vector comprising DNA encoding nonstructural proteins consisting of NS3 and NS4 or a vector comprising a DNA fragment encoding NS5, wherein the size of DNA fragments ranges between 2 to 6kb. Applicants argue that Tang et al do not disclose a vector comprising full length genomic DNA of HCV nor a vector comprising a DNA fragment encoding non-structural NS3, NS4 and NS5 proteins.

In response to Applicant arguments the Office notes that the present claims recite an open claim language with regard to the components of the DNA vaccine. The claims require that the composition of the present invention comprises the claimed DNA fragments. Therefore the claims, as amended read on a DNA vector comprising DNA encoding E1, E2, NS3, NS4 and NS5 proteins. Because both, the Saito's and Tang's constructs comprise DNA encoding E1, E2, NS3, NS4 and NS5 proteins, Tang and Saito anticipate the present claims. Thus the rejection is maintained.

Rejection of claims 1, 2, and 6 under 35 U.S.C. 102(a) as being anticipated by Pancholi et al. (Journal of Virology, January 2003, Vol. 77, p. 382-390) **is withdrawn** in view of Applicant's submission of a certified translation of a foreign priority document.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen, Ph.D./
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648